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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,205	02/15/2005	Michael Cahill	26418U	6456

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EXAMINER	
AEDER, SEAN E	

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,205	CAHILL ET AL.	
	Examiner	Art Unit	
	SEAN E. AEDER	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/8/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/14/08 has been entered.

Claim 52 is pending.

Claim 52 has been amended by Applicant.

Claim 52 is currently under consideration.

Rejections Withdrawn

The rejection of claim 52 under 35 U.S.C. 112 first paragraph, for lacking a written description of genera of peptides, is withdrawn.

The rejection of claim 52 under 35 U.S.C. 112 first paragraph, for failing to comply with the enablement requirement, is withdrawn. However, it is noted that a new rejection under 35 U.S.C. 112, first paragraph, is set-forth below.

Submitted Declarations

The declarations submitted 1/14/08 are acknowledged.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 52 remains rejected under 35 U.S.C. 112, second paragraph, for the reasons stated in the Office Action of 7/13/07 and for the reasons set-forth below.

The Office Action of 7/13/07 contains the following text:

"Claim 52 recites a method for diagnosing disorders associated with prostate cancer comprising contacting eukaryotic cells with peptides; however, the claims do not point-out what result from said contacting would indicate that a subject has a particular disorder. Thus, there is a missing step involving correlating a specific result to a specific diagnosis. See MPEP § 2172.01."

In the Submission of 1/14/08, Applicant states that claim 52 has been amended to clarify that an upregulation in the expression of sialic acid synthase and/or KNP1-beta is detected, thereby delineating the result for the claimed "contacting" that would indicate whether a patient is suffering from prostatic carcinoma.

The amendments to the claims and the arguments found in the Submission of 1/14/08 have been carefully considered, but are not deemed persuasive. In regards to the argument that claim 52 has been amended to clarify that an upregulation in the expression of sialic acid synthase and/or KNP1-beta is detected, thereby delineating the result for the claimed "contacting" that would indicate whether a patient is suffering from

prostatic carcinoma, the claims do not point-out what result from said contacting would indicate that a subject has a particular disorder. The amended claim does not recite that the "upregulation" indicates a particular diagnosis (such as whether or not a patient has prostatic carcinoma); rather, the instant claim recites a result without making a correlation of said result to a particular diagnosis.

Note: The following amendments would obviate this rejection: A method for diagnosing prostatic carcinomas **in a patient**, ~~**wherein**~~ **comprising contacting** ~~**eukaryotic cells**~~ **prostate tissue from said patient** ~~**are brought into contact**~~ with an antibody which is directed against proteins synthesized and/or secreted by carcinomas, wherein the proteins are selected from the group consisting of sialic acid synthase and **KNP-I beta** ~~**KNP1-beta**~~, and wherein **a higher level of said proteins in said prostate tissue, as compared to the level of said proteins in normal prostate tissue,** ~~**an upregulation in the expression of said proteins**~~ **indicates said patient has a prostatic carcinoma** ~~**is detected**~~.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52 remains rejected under 35 U.S.C. 112 first paragraph, for introducing NEW MATTER, for the reasons stated in the Office Action of 7/13/07 and for the reasons set-forth below.

The Office Action of 7/13/07 contains the following text:

"Descriptions of KNP1-beta and methods comprising detecting expression…of KNP1-beta are not found in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the invention was filed, had possession of the claimed invention."

In the Submission of 1/14/08, Applicant argues that KNP1-beta is disclosed in the instant application at page 10 and is detected in Figure 3.

The amendments to the claims and the arguments found in the submission of 1/14/08 have been carefully considered, but are not deemed persuasive. In regards to the arguments that KNP1-beta is disclosed in the instant application at page 10 and is detected in Figure 3, page 10 does not disclose "KNP1-beta". Rather, page 10 discloses "KNP-I beta". Further, Figure 3 does not demonstrate detection of "KNP1-beta"; rather, page 10 discloses detection of "KNP-I beta". Further, the term "KNP1-beta" is not well-known in the art and one of skill in the art would not recognize that "KNP1-beta" is equivalent to "KNP-I beta".

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 52 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for diagnosing prostatic carcinomas in a

patient, comprising contacting prostate tissue from said patient with an antibody which is directed against proteins synthesized and/or secreted by carcinomas, wherein the proteins are selected from the group consisting of sialic acid synthase and KNP-I beta, and wherein a higher level of said proteins in said prostate tissue, as compared to the level of said proteins in normal prostate tissue, indicates said patient has a prostatic carcinoma, **the specification does not reasonably provide enablement for** a method for diagnosing prostatic carcinomas, wherein just any eukaryotic cells are brought into contact with an antibody which is directed against proteins synthesized by and/or secreted by carcinomas, wherein the proteins are selected from the group consisting of sialic acid synthase and KNP1-beta, and wherein just any determination of an upregulation in expression of said proteins is detected, and wherein just any result indicates just any diagnosis for prostatic carcinomas. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in *Ex parte* Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The instant claims are broadly drawn to a method for diagnosing prostatic carcinomas, wherein just any eukaryotic cells are brought into contact with an antibody which is directed against proteins synthesized by and/or secreted by carcinomas, wherein the proteins are selected from the group consisting of sialic acid synthase and KNP1-beta, and wherein just any determination of an upregulation in expression of said proteins is detected, and wherein just any result indicates just any diagnosis for prostatic carcinomas.

The declarations filed 1/14/08 support the specification's disclosure of a method for diagnosing prostatic carcinomas in a patient, comprising contacting prostate tissue from said patient with an antibody which is directed against proteins synthesized and/or secreted by carcinomas, wherein the proteins are selected from the group consisting of sialic acid synthase and KNP-I beta, and wherein a higher level of said proteins in said prostate tissue, as compared to the level of said proteins in normal prostate tissue, indicates said patient has a prostatic carcinoma (see Table 1, in particular).

The state of the prior art dictates that if a marker, such as a particular type of expression of sialic acid synthase in a particular tissue, is to be used as a surrogate for diagnosing a particular disorder associated with prostatic carcinoma, some particular disorder associated with prostatic carcinoma must be identified with the expression of sialic acid synthase. There must be some expression *pattern* that would allow the expression of sialic acid synthase to be used to a particular disorder associated with prostatic carcinoma. For example, Tockman et al (Cancer Res., 1992, 52:2711s-2718s) teach considerations necessary in bringing a cancer biomarker (intermediate end point

marker) to successful application. Tockman et al teaches that prior to the successful application of newly described markers, research must validate the markers against acknowledged disease end points, establish quantitative criteria for marker presence/absence and confirm marker predictive value in prospective population trials (see abstract). Early stage markers of carcinogenesis have clear biological plausibility as markers of preclinical cancer and if validated (emphasis added) can be used for population screening (p. 2713s, col 1). The essential element of the validation of an early detection marker is the ability to test the marker on clinical material obtained from subjects monitored in advance of clinical cancer and *link* those marker results with subsequent histological confirmation of disease. Clearly, prior to the successful application of newly described markers, markers must be validated against acknowledged disease end points and the marker predictive value must be confirmed in prospective population trials (p. 2716s, col 2).

The level of unpredictability for the detection of any disease is quite high. Since neither the specification nor the prior art provide evidence of an association between every determination of "upregulation" of sialic acid synthase or KNP1-beta in every type of eukaryotic cell and prostatic cancer, a practitioner wishing to practice the claimed invention would be required to provide extensive experimentation to demonstrate such an association. Such experimentation would in itself be inventive.

One cannot extrapolate the teachings of the specification to the scope of the claims because the claims are broadly drawn to a method for diagnosing prostatic carcinomas, wherein just any eukaryotic cells are brought into contact with an antibody

which is directed against proteins synthesized by and/or secreted by carcinomas, wherein the proteins are selected from the group consisting of sialic acid synthase and KNP1-beta, and wherein just any determination of an upregulation in expression of said proteins is detected, and wherein just any result indicates just any diagnosis for prostatic carcinomas, and Applicant has not enabled said method because it has not been shown that just any determination of an upregulation of expression of Sialic acid synthase or KNP1-beta in just any eukaryotic cells indicates every diagnosis of prostatic carcinoma.

In view of the teachings above and the lack of guidance, workable examples and or exemplification in the specification, it would require undue experimentation by one of skill in the art to determine with any predictability, that the method would function as broadly claimed.

Note: The following amendments would obviate this rejection: A method for diagnosing prostatic carcinomas **in a patient**, ~~**wherein**~~ **comprising contacting** ~~**eukaryotic cells**~~ **prostate tissue from said patient** ~~**are brought into contact**~~ with an antibody which is directed against proteins synthesized and/or secreted by carcinomas, wherein the proteins are selected from the group consisting of sialic acid synthase and **KNP-I beta** ~~**KNP1-beta**~~, and wherein **a higher level of said proteins in said prostate tissue, as compared to the level of said proteins in normal prostate tissue,** ~~**an upregulation in the expression of said proteins**~~ **indicates said patient has a prostatic carcinoma** ~~**is detected**~~.

Summary

No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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